

SECOND MEDICAL INDICATIONS & THE SWISS- FORM CLAIM: TAMING FRANKENSTEIN'S MONSTER

PART I – SOLVING ONE PROBLEM CREATES ANOTHER

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ABSTRACT

Few patent claim formats present more interpretative difficulties than that of the so-called Swiss-form. Taking shape as purpose-bound process claims – i.e. claims directed towards a manufacturing process applied for a particular end – the Swiss form was originally conceived as an attempt to navigate treacherous waters – waters bordered by two seemingly immutable prohibitions on patenting: the excluded; and the old. A jury-rigged solution to a thorny problem, the Swiss form claim promised to extend patent law’s incentives to the discovery of new and useful functions of existing medicaments: repurposing the old to create the new. For inventions known in other fields, inventions with no prior medicinal purpose, a solution had already been given in statute; Art 54(5) of the European Patent Convention (EPC) 1973 allowed discovery of the first medical use of a known compound to be claimed as a purpose-bound product. Once, however, a first medical use for a compound was known: that was it. Secondary indications, arguably no less beneficial than the first, were left out in the cold. The Swiss-form was devised to bridge this gap: its purpose undoubtedly noble; its proposed effects glittering. However, this virtuous façade conceals a darker underbelly: an underbelly in which the text of the Convention was mutilated and warped, leaving knotty, perhaps intractable, problems in its wake. This then is the story of the Swiss-form: of its birth, its execution, and the more recent attempts to disentangle the legacy of its creation.

The article is split into three parts, each dealing with specific elements of the issue under consideration. This, the first, deals with the adoption of the Swiss-claim within the jurisprudence of the European Patent Office (EPO) and the problems associated with the manner in which the Enlarged Board of Appeal (EBA) of the EPO went about instigating protection for claims to new uses of existing medicaments. It considers the fundamental legitimacy of the format and the hiatus in its interpretation that has only recently been broken. In Part II we visit the specific issues raised by the regulation of the market for prescription medication in the UK. We also consider some patent law fundamentals that have a bearing on the issues that are picked up in Part III, when we finally consider the litigation in *Warner Lambert v Actavis* in depth.

I OUTLINING THE ISSUES

The history of the Swiss form within European Patent law is well documented.¹ Under the European Patent Convention (EPC) as originally enacted there was no explicit mechanism that enabled protection to extend to a newly discovered use of a known medicinal compound. The same was true of new uses in other (i.e. non-medical) fields, but for these there was a work-around. Thus, although a new property of an article could obviously not confer fresh novelty on the old thing in and of itself – the ‘thing’ in question still being known² – processes using the article in new ways could still satisfy the patent bargain.³ In other words, in non-medical fields newly discovered properties and uses of existing things could generally be claimed as methods. Provided these methods also fulfilled the other requirements of patentability – in that they possessed inventive step and were capable of industrial application – a patent could therefore be granted.⁴ Thus if a particular chemical was known to function as a reactant⁵, but was subsequently discovered to act as a catalyst⁶ in certain circumstances, then a process claim could conceivably have been drafted to this new method of use. However, for medicaments there were additional complications which meant that this ‘method’ avenue was blocked. In order to avoid constraining medical practitioners in the performance of their art,⁷ medical methods – methods of treatment, surgery and diagnosis performed on the human or animal body – had

¹ See, for example, Cockbain. J., and Sterckx. S., ‘Is the Enlarged Board of Appeal of the European Patent Office Authorised to Extend the Bounds of the Patentable? The G5/83 Second Medical Indication/EISAI and G2/08 Dosage Regime/ABBOTT RESPIRATORY Cases’, (2011) 42 *IIC* 257. More recently, Bosytyn has also explored some of the history of the claim format. See Bostyn. S., ‘Medical treatment methods, medical indication claims and patentability: a quest into the rationale of the exclusion and patentability in the context of the future of personalised medicine’, [2016] *IPQ* 203.

² And therefore not new in the sense required by Art 54 EPC 1973.

³ In that the public would be getting something from the patentee that they had not had access to before.

⁴ See, for example, the discussion of this point in Blanco-White, T.A., *Patents for Inventions*, (4th Ed, 1974, Stevens & Sons; London), at pp.19-20.

⁵ i.e. a reagent that is consumed by use in the chemical reaction.

⁶ i.e. a reagent that increases the rate of a reaction but is not consumed by use.

⁷ G_05/83 *EISAI/Second Medical Indication* [1985] OJ EPO 64; [1979-85] EPOR B241, at point 22 of the Reasons for the Decision. The Enlarged Board made similar comments some years later in G_02/08 *ABBOTT RESPIRATORY/Dosage Regime* [2010] OJ EPO 456; [2010] EPOR 26 when it stated, at point 5.3 of the Reasons for the Decision that: the exclusion was included because “physicians should be free to take all actions they considered suitable to prevent or to cure a disease, and in this exercise they should remain uninhibited by patents.”

been excluded from patentability under Art 52(4) EPC 1973.⁸ Accordingly, claims to the new use of a known compound in medicine were trapped between a rock and a hard place. The compound was old and therefore not novel in and of itself, and the novel use was unable to be claimed directly because of the statutory exclusion.

In the early stages of discussions leading up to the EPC, indeed until a point following the adoption of a second preliminary draft of the Convention,⁹ this approach was to be universal within the medical field. If a substance was already known then its prospects of gaining subsequent patent protection for a new medical use were nil. For many in “interested circles”¹⁰, however, this was considered to be an unfortunate, and overly restrictive, position. Accordingly, following pressure from these parties, limited respite from the harshness of this rule as far as it related to the *first* use in medicine of compounds known in other fields had been achieved during the drafting process. Thus Art 54(5) EPC 1973 allowed a patent to be granted for the new use of a known substance or compound provided its use in “*any method* referred to in ...[Art 52(4)] is not comprised in the state of the art” (emphasis supplied). Second (and subsequent) uses were, however, left out in the cold. Some years later, in a display of what might be charitably called creative lawyering, the Enlarged Board of Appeal (EBA / Enlarged Board) of the European Patent Office (EPO) ‘remedied’ this situation by extending the reach of the Convention. Accordingly, in G_05/83 *EISAI/Second Medical Indication*,¹¹ the EBA cast off its interpretative shackles and created a mechanism by which claims to second and subsequent uses of medicinal compounds could also gain recognition within the then extant system. To achieve this goal, the Board adopted the so-called Swiss-form of claim: “use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application”.¹²

⁸ This sentiment was originally enacted within Art 52(4) EPC 1973. Following revision by Diplomatic Conference in November 2000, the relevant provision can now be found in Art 53(c) EPC 2000.

⁹ This occurred at the 4th meeting of the Intergovernmental Conference for the setting up of a European System for the Granting of Patents held in Luxembourg from 20 to 28 April 1971. See *Press Release* dated 28 April 1971, Doc No. BR/122/e/71 (Press 32).

¹⁰ This term is used to refer to the interveners in the *Minutes of the 9th Meeting of Working Party I* (Brussels, 17 Nov 1971) Doc No. BR/135/71 at [92].

¹¹ [1985] OJ EPO 64; [1979-85] EPOR B241. This was one of several cases referred to the Enlarged Board of Appeal on the question of second medical use. Associated decisions in Case G_01/83 *BAYER/Zweite Medizinische Indikation* [1985] OJ EPO 60, and G_06/83 *PHARMUKA/Deuxième Indication Médicale* [1985] OJ EPO 67 were published in their original German and French texts only.

¹² G-05/83 *EISAI/Second Medical Indication* [1985] OJ EPO 64; [1979-85] EPOR B241, at Point 23 of the Reasons for the Decision.

Shortly thereafter the EBA's approach became embedded (begrudgingly in some cases)¹³ in the national law and practice of the member states that subscribed to the EPC.

By directing the claim to the *manufacture* of a medicament, the Swiss-form was said to avoid the prohibition on methods of treatment under Art 52(4) EPC 1973. Furthermore, despite the steps of manufacture themselves potentially being no different from that in the state of the art, it provided a mechanism through which to channel novelty from the verboten use that was sufficient to support a patent. Validity was therefore borrowed from the forbidden methods in order to validate the grant, allowing known compounds to be transformed once more into something new enough to satisfy the broad definition laid down in Arts 54(1) and (2) EPC by innovative use in the medical field.

Whether this act of 'interpretation' of the Convention by the Enlarged Board was a legitimate or ultra vires expression of its powers is a debate for another time. Nevertheless, ever since the Swiss-form's inception, concerns have been raised both over its fundamental legitimacy and the probable difficulties that would arise upon attempting to construe its language in actions for infringement.¹⁴ Indeed, these concerns were such that the provisions which formed the bedrock of the EBA's decision to embrace the Swiss-claim format, i.e. those covering methods of treatment and the medical use of compounds, were extensively redrafted when the EPC was amended in November 2000¹⁵ – what might be described as an ex-post legislative tidying of the mess created by the Enlarged Board in EISA I.

Upon the revised text's entry into force, reference was made once more to the Enlarged Board to consider the effect of the new statutory language. Its decision in G_02/08 *ABBOTT RESPIRATORY/Dosage Regime*¹⁶ was uncompromising: the use of the Swiss-form claim was an

¹³ See, for example, *Wyeth / Schering's Application* [1985] RPC 545 (UK).

¹⁴ See, for example, Patterson, G., 'The Novelty of Use Claims', (1996) 27 *IIC* 179, at 180; Cockbain J. & Sterckx S., 'Is the Enlarged Board of Appeal of the European Patent Office Authorised to Extend the Bounds of the Patentable?', (2011) 42 *IIC* 257, at 271. Expressions of concern can also be found, for example, in *Wyeth / Schering's Application* [1985] RPC 545, and *Bristol Myers Squibb v Baker Norton* [1999] RPC 253. See also Pagenberg's comments on Wyeth/Schering in (1986) 17 *IIC* 101, at 115. Also *ABBOTT RESPIRATORY*, discussed below.

¹⁵ At a Diplomatic Conference of Ministers held in Munich in November 2000. A comparison of the amended text with that of the EPC 1973 can be found in 'Synoptic Presentation EPC 1973/2000 – Part I: The Articles' [2007] *Special Edition No. 4 OJ EPO 1*, at 52-55.

¹⁶ [2010] OJ EPO 456; [2010] EPOR 26.

“adequate but exceptional solution”¹⁷ to the problem of enabling protection for second medical indications under the EPC 1973 which could no longer be sustained. Following revision of the Convention, the “loophole” existing in the old provisions that had required the Swiss-form framework to navigate had been closed and thus: “when the reason of the law ceases, the law itself ceases.”¹⁸ In the post-revision landscape, the claim format was deemed unnecessary and unsafe: not to be used in subsequent patents for second medical indications.¹⁹ Instead use-bound product claims, i.e. “use of X for the treatment of Y”, allowable under the new Articles 54(4) and (5) EPC 2000 for first and subsequent medical indications respectively, were to be used in their place. Nevertheless, “[i]n order to ensure legal certainty and to protect legitimate interests of applicants”, the EBA acknowledged that its decision should have “no retroactive effect”. Instead it gave a three month transitional window following the publication of the decision in the Official Journal²⁰ for the prospective phasing out of the untidy Swiss-form. Accordingly, by 29 January 2011²¹ all new applications were required to comply with the change in claim format. Existing patents and applications made, or claiming priority before this date, however, could still utilise the Swiss-form claim and enjoy the attendant “legal uncertaint[ies]”²² that accompanied it.

As of 2017, therefore, the Swiss-form lives on borrowed time – the last patent containing claims written in this way will, all things being equal, expire at the end of January 2031 (or 2036 if Supplementary Protection Certificates are included in the equation). However, there has recently been renewed interest paid to the moribund format as the difficulties of its construction have finally bubbled to the surface. The past 12-18 months in the UK have therefore seen perhaps

¹⁷ [2010] OJ EPO 456, at Point 7.1.1 of the Reasons for Decision; [2010] EPOR 26, at [133]

¹⁸ Ibid, at Point 7.1.2 of the Reasons for Decision.

¹⁹ See *ibid.* Point 7.1.3 of the Reasons for Decision, which contains comments concerning the inadequacy of the claim format as well as voicing of the prohibition on its use.

²⁰ Ibid. at [7.1.4]. The decision of the EBA in *ABBOTT RESPIRATORY* was reported in the 10th edition of the Official Journal of the EPO in 2010, [2010] OJ EPO 456. This was published online on the 28th October 2010. See: <https://www.epo.org/law-practice/legal-texts/official-journal/2010.html>.

²¹ See the notice from the EPO concerning non-acceptance of claims in the Swiss form published in the Official Journal [2010] OJ EPO 514.

²² See [2010] OJ EPO 456 at [5.10.4], where reference is made to the explanatory notes established by the Swiss delegation and annexed to the basic proposal of the revised wording of Art 54 EPC. See further document MR/18/00 at point 4, available here: [http://documents.epo.org/projects/babylon/eponet.nsf/0/B4BA2517EDEF4701C1257280005F454E/\\$File/mr00_018_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/B4BA2517EDEF4701C1257280005F454E/$File/mr00_018_en.pdf).

the most activity in this field in its short life, a position mirrored in a number of other EPC Contracting States. Following no less than five appearances before Mr Justice Arnold, in addition to two trips to the Court of Appeal, the saga of *Warner Lambert v Actavis*²³ provides an interesting, indeed critical, exploration of the problems connected with the interpretation of the Swiss form claim.

For a legal development that is now over 30 years old it is somewhat surprising that it has taken so long for these issues to arise. This hiatus is all the more striking when it is considered that the format's flaws had been highlighted in both judicial decisions and academic commentary for much of its short life.²⁴ However, as we shall see, determining the scope of the Swiss form is not a straightforward affair – indeed, when considered in the abstract, one commentator famously noted that it was a format whose interpretation was “hardly possible”.²⁵ Possible or not, it is clear that the act of its construction raises fundamentally difficult questions of function and form, policy and purpose. At the end of the day, the Swiss form may be the product of the Enlarged Board's good intentions, but as we all know the road to Hell is paved with similar material.

When initially incorporated into the Convention, Article 54(5) EPC 1973 (which was, in part, to form the basis for the adoption of the Swiss-form) was prophetically described by Otto Bossung as a “cuckoo's egg”²⁶ – a provision foreign to the majority of the contracting States that might

²³ At first instance see *Warner-Lambert v Actavis* [2015] EWHC 72 (Pat) (Arnold J; interim injunction), [2015] EWHC 2548 (Pat) (Arnold J; full trial) as well as a number of other related decisions in the case (all before Arnold J): [2015] EWHC 223 (Pat); [2015] EWHC 249 (Pat); and [2015] EWHC 485 (Pat). The Court of Appeal's decision on the interim matter was handed down in May 2015 – [2015] EWCA Civ 556 (CoA), and the decision at full trial in October 2016 – [2016] EWCA Civ 1006. Related matters concerning the same patent formed the basis of *Warner-Lambert Company LLC v Sandoz GmbH & Ors* [2015] EWHC 3153 (Pat).

²⁴ See note 14, above.

²⁵ Trüstedt W., ‘Der Patentschutz für chemische Erfindungen nach der Rechtsprechung des Bundesgerichtshofs’, [1974] *Chem. Ing. Techn.* 529, at 535. Trüstedt, admittedly gives no detailed reasoning to back up this view... The full quote, in German, reads: “Ein Schutz für eine Zweitindikation, also für den Wirkstoff, der bereits pharmazeutischen Zwecken dient und bei dem eine weitere pharmazeutische Verwendung gefunden wird, ist über die Konstruktion eines Herstellungsverfahrens kaum möglich.” Also discussed in Uttermann J., ‘Purpose-bound Process Claims for Pharmaceuticals – Two Solutions for the Second Indication’, (1986) 17 *IIC* 41, at 45-6.

²⁶ See O. Bossung, “Erfindung und Patentierbarkeit im Europäischen Patent recht” [1974] *Mitteilung der deutschen Patentblatt* 101, at 126. It is somewhat ironic that Bossung was among the seven members of the EBA that presided over the EISA decision and was therefore responsible for realising his own prophesy. The remainder of the panel were Romauld Singer, Peter Ford, Roger Kämpf, M Prélôt, George S.A. Szabo and J.A.H. van Voorthuizen.

contain something unexpected. By hijacking the Convention and unilaterally extending its reach, the EBA played Frankenstein, hatching and augmenting this cuckoo, creating a monster that is both impractical and incompatible with the fundamentals of patent law. Now the EBA's Franken-cuckoos have now come home to roost. This is their story. In telling this tale, we consider some of the issues surrounding the Swiss form's most trenchant problem – the question of its scope. We explore how these questions came to a head in the *Warner Lambert* litigation, and also ask whether the approaches adopted provide adequate solution to the problems raised. This last issue is perhaps the most critical, for as we shall see, this case may be the first of many over the next few years which have to deal with these difficulties. First, however, we turn to consider some of the background that led to the EBA's actions.

II THE BIRTH OF A CLAIM FORMAT

As already noted, when the European Patent Convention was first promulgated it made no provision for the protection of new uses of existing medical compounds. Accordingly, from the time it opened its doors to applicants,²⁷ the practice of the EPO's Examining Division, responsible for initial decisions on patentability under the EPC, was to reject claims directed to such subject-matter.²⁸ It was reasoned that claims directed to a new use of a known medicament fell foul of the Convention in one of two ways. Either they were directed at the process of using the compound and were thereby prohibited under Art 52(4) EPC 1973 as methods of treatment of the human body by therapy, surgery or diagnosis – all of which were considered incapable of industrial application. Alternatively, they were directed at a product and hence claimed something old. Moreover, as the compound's first use in therapy was already known, the patentee could not avail themselves of the limited safe harbour created by Art 54(5). Based on this logic, rejection of such claims was evidently the only option.²⁹

²⁷ The European Patent Office opened its doors to applications for patents on 1 June 1978.

²⁸ The opinion in G_05/83 *EISA/Second Medical Indication* [1984] OJ EPO 581; [1979-85] EPOR B241, discussed below, arises from a number of appeals made against refusal of European patent applications for new uses of known pharmacologically active compounds. Indeed, as Bruchhausen notes, the EPO's own Guidelines for Examination which were in operation before the EISA decision of the EBA adopted the view that Art 54(5) only applied to the first medical use. See Bruchhausen, "The Second Medical Use of Medicaments in European Patent Law", (1985) 17 *IIC* 306 at p.308.

²⁹ See for example, the outline of the Examining Division's reasons for rejection in T_17/81 *BAYER/Nimopidin* [1983] OJ EPO 266; [1979-85] EPOR B320.

This all changed, however, with the decision of the Enlarged Board of Appeal in G_05/83 *EISAI/Second Medical Indication*³⁰ and the consequent adoption of the Swiss-form claim. Here the Board reasoned that by directing the claim to the manufacture of a medicament, it could avoid the prohibition on medical methods. The manufacturing step was, after all, not directed at administration of the compound, and moreover could obviously be carried out on an industrial basis. As such, it could not fall foul of the prohibition on patenting medical methods. The Board acknowledged that there could be complications where the “medicament resulting from the claimed use is not in any way different from a known medicament.”³¹ However, it considered the problem could be solved by drawing analogy with the provisions governing the patentability of a first medical use of a known compound. It therefore explained that in such cases the requisite novelty would be derived from the new use itself, and that this was the case despite claims to the use per se being prohibited. The Board continued, stating that Art 54(5) therefore provided an exception to the general rule that could be conceived as a “special approach to the derivation of novelty that can only be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC [1973].”³² In other words, despite there being nothing in the Convention to support this view, the EBA declared that it was a principle that could be separated from the language of the Article itself and made of general application in this limited field. Disappearing further down the rabbit-hole to Wonderland, the Board then explained that it could “not deduce from the special provision of Article 54(5) EPC that there was any intention to exclude second and further medical indications from patent protection other than by a purpose-limited product claim.” In addition, no such exclusionary principle could be derived either from “the terms of the European Patent Convention; nor can it be deduced from the legislative history of the articles in question.”³³

The absurdity of the Board’s logic cannot escape comment. At its core what was stated was that the absence of a provision specifically excluding protection for a thing that would *already be unpatentable* on other grounds could be used to infer that the unpatentable thing should in fact be considered patentable. Edward Lear would be proud. The exclusionary principles found within the requirement of novelty (excluding the old) and the prohibition on patenting medical methods were apparently not clear enough in this regard. In addition, the fact that specific legislative

³⁰ G_05/83 *EISAI/Second Medical Indication* [1985] OJ EPO 64; [1979-85] EPOR B241.

³¹ Ibid. at Point 20 of the Reasons for the Decision.

³² Ibid. at Point 21 of the Reasons for the Decision.

³³ Ibid. at Point 22 of the Reasons for the Decision.

provision had to be made to circumvent these hurdles in cases where an old thing was used for the *first* time in medicine appears to have been used to support the Board's claim rather than contradict it. Surely, if the rules are such that a thing, X, is excluded from protection unless space is specifically carved out to allow for its existence, then the fact that space is not also carved out for other things, Y, is indicative of the fact that protection of Y is not desired? Nevertheless, the Board concluded that claims for second and subsequent medical indications of products already known to be effective in the field of medicine would be allowed provided they were drafted in the Swiss-form: "use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application."³⁴ Furthermore, this format was stated to be acceptable even where "the process of manufacture as such does not differ from known processes using the same active ingredient."³⁵

And so the Swiss-form claim was born. However, as might be assumed from the foregoing discussion, there are a number of problems with the approach taken by the EBA. Thus, in addition to the fatally flawed logic that led it to its conclusion, the Board conveniently overlooked the fact that the safe harbour that had been created under Art 54(5) EPC 1973 was only ever intended to shield first medical use from hurricane 'novelty'. Such is clear not only from the explicit language used – provided its use in "*any method* referred to in ...[Art 52(4)] is not comprised in the state of the art" – but also from the travaux préparatoires of the EPC 1973. A subject to which we now turn our attention.

A Legislative History of Art 54(5) EPC 1973 – a fundamentally limited provision

As noted above, the Enlarged Board of Appeal in EISAI considered that Art 54(5) EPC 1973 contained a principle that could be separated from the language of the provision itself and made of general application. Moreover, having apparently conducted its own investigation of the negotiations leading up to the final text of the EPC, the Board could find "no intention to exclude" patents on second and subsequent medical indications.³⁶ Clearly it was not trying very hard. Even a cursory reading of the final stages of the negotiations leading up to the passage of the EPC would appear to place beyond doubt the intention of the Member State delegations to exclude second and subsequent medical indications from patent protection. The minutes of the

³⁴ Ibid. at Point 23 of the Reasons for the Decision.

³⁵ Ibid.

³⁶ Ibid. at Point 22 of the Reasons for the Decision.

Munich Diplomatic Conference at which the Member States agreed and signed the final text of the Convention make the point eminently clear:

“The Netherlands delegation proposed that the wording of [Article 54(5) EPC 1973] ... should be improved. It said that on no account did it wish ... to break away from the principle that only the first application in respect of the use of a known substance or composition in a method for treatment of a human or animal body by surgery or therapy is patentable, and not the second and subsequent applications.”³⁷

Furthermore:

“The Chairman ... said that, in his opinion, the aim in [Article 54] paragraph 5 was to make clear that a known substance (or a known composition) which, since it formed part of the state of the art, was no longer patentable, nevertheless could be patented for the first use in a method for treatment of the human or animal body by surgery or therapy; however, a further patent could not be granted if a second possible use were found for the same substance, irrespective of whether the human or animal body was to be treated with it.

The Chairman noted that his views were shared by the Government delegations.”³⁸

Separately, the report of Paul Braendli, then Vice-Director of the Swiss Federal Intellectual Property Office,³⁹ which detailed the results of Main Committee I’s proceedings (and dealt with all substantive issues of patentability) was unequivocal on this matter:

“An improved wording of [Article 54(5)] ... now ensures the patentability of known chemicals for such uses in therapeutic and diagnostic methods as do not form part of the state of the art. In this connection the Main Committee was also of the opinion that **only**

³⁷ *Minutes of the Munich Diplomatic Conference for the setting up of a European System for the Grant of Patents* (1973, Munich), Doc No. M/PR/I at [54].

³⁸ *Minutes of the Munich Diplomatic Conference for the setting up of a European System for the Grant of Patents* (1973, Munich), Doc No. M/PR/I at [57] to [58].

³⁹ Braendli became the second President of the EPO in 1985, taking over from Johannes Bob van Benthem.

a **first use**, irrespective of whether it is with regard to humans or animals, fulfils the requirements of this provision.”⁴⁰ (emphasis supplied)

Indeed, if the Board had conducted a systematic exploration of all of the supporting documents in the travaux préparatoires of the EPC 1973⁴¹ it would have found little, if anything, to support the view that the member states intended any other position to be adopted. Nevertheless, the seven members of the Enlarged Board in EISAI, at least three of whom were actually present at the Munich Diplomatic Conference,⁴² considered (following their “own independent studies of the preparatory documents”)⁴³ that the matter had been left sufficiently open to allow them to conclude that:

“No intention to exclude second (and further) medical indications generally from patent protection can be deduced ... from the legislative history of the articles in question.”⁴⁴

This conclusion was reached notwithstanding a contemporary summary of the Munich Conference written by one of the self-same members of the EBA which decided EISAI (Romauld Singer) which points firmly against such a result. Accordingly, Singer, writing in 1974, explained that during the Munich Conference the text of Art 54(5) EPC 1973 underwent amendment so that a more comprehensible formulation could be obtained. The resulting language, he suggested, allowed the patentability of the first medicinal use of a known substance

⁴⁰ Report by Paul Braendli, Lic. iur., Vice-Director of the Federal Intellectual Property Office (Switzerland) on the results of Main Committee I's proceedings, at Annex I to the *Minutes of the Munich Diplomatic Conference for the setting up of a European System for the Grant of Patents* (1973, Munich), at p. 184. This is the same document that can be found numbered as Doc No. M/148/G (Munich, 1 Oct 1973). The relevant passage can be found on p.4 thereof.

⁴¹ Now available online arranged according to Article at <http://www.epo.org/law-practice/legal-texts/archive/eepc-1973/travaux.html>. Access to a complete set of documents arranged by document number and otherwise unedited is available from the EPO by request.

⁴² The EISAI panel consisted of Otto Bossung, Romauld Singer, Peter Ford, Roger Kämpf, M Prélôt, George S.A. Szabo and J.A.H. van Voorthuizen. Singer was part of the German delegation at the Munich Diplomatic Conference, and Bossung was also present as “Adviser” to the German delegation. Kämpf was part of the Swiss delegation. See the List of Participants in the *Minutes of the Munich Diplomatic Conference for the setting up of a European System for the Grant of Patents* (1973, Munich), at p.211-237.

⁴³ G_05/83 *EISA/Second Medical Indication*, [1985] OJ EPO 64; [1979-85] EPOR B241, at Point 22 of the Reasons for the Decision.

⁴⁴ Ibid.

or composition for therapeutic purposes, but confirmed that further inventive use of the same substance for medical purposes should be excluded from patentability.⁴⁵

While obviously providing a consensus judgment, the Enlarged Board in EISAI did explicitly state that it had undertaken its own “independent study of the preparatory documents” in order to come to the conclusion that the second medical use should not be excluded. It is not inconceivable therefore that, in theory at least, Singer had changed his mind upon re-examining the published travaux préparatoires a decade on from his original analysis. Nevertheless, in light of the clear expressions of sentiment from the minutes of the Munich Convention outlined above, and this author’s own research into the process of drafting the EPC, it is difficult (if not impossible) to see how this could be the case.

Ill-Fitting Solutions Create Further Problems

By extending the principle of Art 54(5) EPC 1973, if not the provision itself, to the case of second and subsequent medical indications, the Enlarged Board constructed a framework that overcame the technical patentability obstacles that lay in its path. In doing so, it jumped boldly over the picket-fence that marked the boundary of its remit as interpreter of the Convention and trespassed upon the legislative lawn. To add insult to injury, it also painted a false picture of the EPC drafters’ intent – a distorted representation to legitimise legislation in the name of interpretation. However, perhaps the most galling aspect of the original decision was the fact that, having ridden roughshod over the text of the Convention in the guise of interpreting it, the Board then hid behind provisions of the same in order to avoid construing the claim. Downstream problems of interpretation were not its concern: “It is particularly important to bear in mind that Article 64(3) leaves questions of infringement to be dealt with by national law.”⁴⁶

Mr Justice Jacob (as he then was) remarked in uncharacteristically restrained tones in *Bristol Myers Squibb v Baker Norton*⁴⁷ that the EBA’s refusal to consider the downstream effects of its decision in EISAI was “not helpful”. He continued, noting that by failing to consider the full repercussions of the approach adopted, the Enlarged Board created a situation that left

⁴⁵ Singer, R., ‘Das materielle europäische Patentrecht’, [1974] *GRUR Int* 61, at 64.

⁴⁶ G_05/83 *EISAI/Second Medical Indication*, [1985] OJ EPO 64; [1979-85] EPOR B241, at Point 18 of the Reasons for the Decision.

⁴⁷ [1999] RPC 253.

“intractable problems for an infringement court—and for the public who need to know what they can and cannot do.”⁴⁸ Moreover in its comments concerning the effect of Article 64(3) EPC, the Board significantly misstated the provision’s effects. Therefore, rather than the broad proclamation the EBA had used to justify its lack of interest in the downstream effect of its decision, the actual wording of the Article is far narrower: “Any infringement of a European Patent shall be dealt with by national law.” This, as Jacob J explained, “does not mean that questions of validity (especially novelty) or extent of protection are matters for national law. On the contrary both are specifically matters covered by the EPC...”.⁴⁹ Alan White made a similar point some years earlier when he stated that: “It is ... not possible to divorce questions of infringement from considerations of validity, because both depend on the construction to be placed on the claim in question. That claim construction should be decided without reference either to the prior art or to the alleged infringement and, only when this has been done, can it be decided whether such a claim is valid and, if so, infringed.”⁵⁰

By sidestepping difficult issues of construction in order, ostensibly, to avoid questions of infringement, and closing its eyes to the downstream effect of its decision, the Enlarged Board of Appeal therefore created a time-bomb. Generations of patentees have relied upon the fact of the Swiss-form’s existence as evidence of their patents’ worth. For some, this will have been sufficient: the mere fact of the patent grant being all that is needed to attract capital or to effect the transfer of rights to others. Still more will have used evidence of the patent’s existence as a bargaining chip, throwing its weight into complex transactions with little concern for detailed consideration of its power to prevent the marketing of competing compounds in anything other than an abstract sense.⁵¹ However, for many the *raison d’être* of the grant of a patent is the right to exclude, and the right to exclude is determined by the scope of the claims. It was therefore only a matter of time before the EBA’s chickens came home to roost and the limits of the claim format’s protection were tested. In many respects it is amazing that this process took as long as it did.

⁴⁸ [1999] RPC 253, at p.272.

⁴⁹ [1999] RPC 253, at p.272.

⁵⁰ White A.W., ‘Patenting the Second Medical Indication’, [1985] *EIPR* 62, at p.63.

⁵¹ For a discussion of some of the many different motivations that may lie behind a decision to patent and which are essentially unconnected with enforcement of the right against infringers see Fisher. M., *Fundamentals of Patent Law: Interpretation and Scope of Protection*, (2007, Hart, Oxford), at pp.93-7.

III INTERPRETATIVE HIATUS

Prior to the recent *Warner-Lambert* litigation,⁵² neither the English courts nor the Boards of the EPO had really engaged with the question of interpreting the intricacies of the Swiss-form claim.⁵³ English decisions had mostly concentrated on issues of validity. Accordingly, there were a number of authorities supporting the contention that the Swiss claim was directed to the manufacture of a medicament and not to the use of compound: notwithstanding that this latter element was the thing that provided novelty.⁵⁴ English cases have also confirmed that the Swiss claim must relate to a *process* of manufacture; to interpret it otherwise, as a “product when used ... would constitute a method of treatment which is prohibited under the EPC.”⁵⁵ In terms of construction, however, about the closest that the English courts had got to the interpretation of the claim in any substantial manner was *Hospira v Genentech*.⁵⁶ Here Birss J explained that it was common ground between the parties that the word “for” in the claim meant “suitable and intended for”.⁵⁷ This was, however, as far as the judge got on this issue.

Prior to the enactment of the EPC, the German courts had concluded⁵⁸ that a straightforward purpose-limited product claim – i.e. use of an existing medicament for the treatment of a new disease – should be interpreted as including at least the preparation of a pharmaceutical product with accompanying instructions for use in the treatment of the illness.⁵⁹ This entire package

⁵² Discussed in detail in Part III of this series.

⁵³ The same can be said of a number of other European jurisdictions. As indicated in the *Warner Lambert* decisions – see especially those of the Court of Appeal in the interim matter: [2015] EWCA Civ 556 at [72] to [98]; and at full trial: [2016] EWCA Civ 1006 at [189] to [201] – a flurry of interest has been paid to the scope of the Swiss-form only since approximately 2013. Nevertheless, it is only since approximately 2015 that the issue has undergone serious analysis.

⁵⁴ See, for example, *Wyeth / Schering's Application* [1985] RPC 545, where the Court (Whitford & Falconer JJ sitting *en banc*) stated (at p.563) that: “the Swiss form of claim is directed to the use of the known substance in the manufacture of the medicament for a new therapeutic use, and is not directed to claiming the or any instruction for the new therapeutic use as the invention.” Similarly, in *Actavis v Merck* [2009] 1 WLR 1186, Jacob LJ noted (at [75]) that the Swiss-form claim: “is not aimed at and does not touch the doctor – it is directed at the manufacturer”.

⁵⁵ *Bristol Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1 at [40] per Aldous LJ.

⁵⁶ *Hospira UK Ltd v Genentech Inc* [2014] EWHC 1094 (Pat).

⁵⁷ *Ibid.* at [58].

⁵⁸ In cases such as *Benzolsulfonylharnstoff* (1978) 5 IIC 42.

⁵⁹ Although as Cockbain & Sterckx note: “Here it should be borne in mind that prior to the EPC coming onto effect in 1978, the German courts had a somewhat “relaxed” attitude towards the wording of patent claims.” See Cockbain, J., and Sterckx, S., ‘Is the Enlarged Board of Appeal of the European Patent Office Authorised to Extend

approach (referred to in German as *augenfällige Herrichtung*) was endorsed under the German implementation of the EPC⁶⁰ by the German Federal Supreme Court (the *Bundesgerichtshof* (BGH)) in *Hydropyridin*.⁶¹ Here, in a judgment that arguably stretches the envelope of credibility to breaking point, the German court considered that a medicinal use claim (i.e. use of X to treat Y) should be interpreted as concentrating attention on the (ostensibly unclaimed) preparatory manufacturing and packaging steps. In other words, whereas standard method claims were directed at the administration step (what might in this context be considered the actual use of the compound for the treatment of the illness or disease), a medicinal “use” claim was functionally presumed to cover only steps leading up to the administration of the medicine – i.e. up to, but not including the use itself. Given this fiction, the court considered that claims to the “use” of a compound in medicine would not be caught by the exclusion within Art 52(4) EPC 1973 – this was reserved for method claims *per se*. “Use” under this view is therefore interpreted as excluding the very thing to which it refers. Sterckx and Cockbain describe this presumption as “ridiculous”;⁶² it is difficult to disagree with their assessment. Nevertheless, the BGH continued, explaining that as these ‘preparation and packaging steps’ self-evidently were capable of industrial application then a patent should be forthcoming. As Meier-Beck notes, the Convention’s exclusion⁶³ of purpose-related product protection for the discovery of a further medical use was considered to say nothing about whether protection should be similarly excluded in other circumstances.⁶⁴ In particular, where claims to use-inventions were construed as being limited to providing protection for a substance made-up for the therapeutic treatment and its subsequent application for that new treatment, then this silence was truly golden. In this latter circumstance, the BGH took the view that the industrial application “precondition was met by the mere possibility of using the invention in industry, and that any other feasible uses were beside the point”⁶⁵.

the Bounds of the Patentable? The G5/83 Second Medical Indication/EISAI and G2/08 Dosage Regime/ABBOTT RESPIRATORY Cases’, (2011) 42 *IIC* 257 at p.259 fn 9.

⁶⁰ The provisions in question were implemented under the Patent law of 1981.

⁶¹ BGHZ 170, 215; [1983] GRUR 729. An English translation can be found in [1984] OJ EPO 26.

⁶² Sterckx, S. & Cockbain, C., *Exclusions from Patentability* (2012; CUP; Cambridge), at p.160.

⁶³ Strictly speaking, this would be better expressed as its failure to embrace: purpose-related product protection was, after all, only excluded by implication from the fact that Art 54(5) EPC 1973 was limited to the first use in medicine.

⁶⁴ Meier-Beck P., ‘Patentschutz für die zweite medizinische Indikation und ärztliche Therapiefreiheit’ [2009] *GRUR* 300, at p.302.

⁶⁵ Bruchhausen K., ‘The Second Medical Use of Medicaments in European Patent Law’, (1985) 16 *IIC* 306, at 309.

The German *Hydropyridin* decision “peacefully co-existed” with that of the EBA in EISAI for more than 20 years – “Practical relevance [having] not been achieved by the different approaches, as far as they can be seen”⁶⁶ during this time. Indeed, as Schneider was to remark in 2008: “Germany still follows the *Hydropyridin* decision ... and re-interprets the Swiss-type claims, granted by the EPO, as use claims.”⁶⁷ However, this is not to say that the two were in absolute conformity and to treat them as synonymous would be a mistake. The German approach, after all, treats the claim as a product and requires meaningful preparation of the entire pharmaceutical package in order that the object of the use claim is satisfied. This evidently differs in form and content from a claim to a manufacture (as required under the Swiss-form). Indeed, as Meier-Beck explains, any claim of absolute harmony between the approaches which suggests there are “no substantive differences in the subject matter or scope of the patentable, or in the effect of the patent granted in one or the other version against third parties” is a result “obtained only in intricate ways”.⁶⁸ Accordingly, while evidencing one approach that has been used to deal with the Swiss-form, it is clear that there is little within the *Hydropyridin* formulation that is of general application to the question of the claim format’s scope unless one is to accept that claims to purpose-bound processes can be interpreted as purpose-bound products. Most are not willing to stretch credulity in this manner.

In terms of offering interpretative clarity, things were no better in the Boards of the EPO. Decisions subsequent to EISAI extended the application of the Swiss-form to a vast array of new ‘uses’ with ever diminishing distinction between the old and the new. Accordingly, patents have been granted in cases where novelty is derived from the class of patient treated (sero-negative versus sero-positive pigs⁶⁹), the technical effect of the use (making dental plaque removal more effective versus reducing the solubility of tooth enamel in organic acids⁷⁰), and the

⁶⁶ Meier-Beck P., ‘Patentschutz für die zweite medizinische Indikation und ärztliche Therapiefreiheit’ [2009] GRUR 300, at p.303 – translated from the original German by this author.

⁶⁷ Schneider D.R., ‘Patenting of Pharmaceuticals – Still a Challenge?’ (2008) 39 IIC 511, at p.516. Schneider cites the BGH decision in *Trigonellin* [2001] GRUR 730 in support of this proposition.

⁶⁸ Meier-Beck P., ‘Patentschutz für die zweite medizinische Indikation und ärztliche Therapiefreiheit’ [2009] GRUR 300, at p.303.

⁶⁹ T_19/86 *DUPHAR/Pigs II* [1989] OJ EPO 24; [1989] EPOR 10. Similarly see T_893/90 *QUEEN’S UNIVERSITY KINGSTON/Controlling Bleeding*, unreported decision of the TBA dated 22 July 1993 (haemophiliacs vs. non-haemophiliacs).

⁷⁰ T_290/86 *ICI/Cleaning Plaque* [1991] EPOR 157

mode of administration (subcutaneous versus intramuscular administration⁷¹). Swiss-form claims have also been allowed to derive novelty from the sub-population of patients treated;⁷² the frequency of drug administration;⁷³ cases where the patent claims a novel clinical situation (e.g. targeting tumour vasculature rather than the cancer cells themselves⁷⁴); and a new dosage regime.⁷⁵ Each new “indication” stretches the thread of novelty still further, and raises the potential for the territory surrounding any given medicament to become more and more heavily populated. However, notwithstanding the proliferation of decisions extending the Swiss-form’s grasp, on the issue of construction the silence was deafening. Indeed, until very recently about the best that could definitively be said was that the format should be understood as a process claim and that this was accordingly narrower than the purpose-bound product protection allowable for first medical indications under Art 54(5) EPC 1973/Art 54(4) EPC 2000, and for second medical indications under EPC 2000.⁷⁶ More recently, the TBA has gone slightly further and indicated that it would be impermissible to amend a patent containing a Swiss-form claim so as to turn it into a use-limited product, as this would extend the scope of the grant.⁷⁷ The Swiss-

⁷¹ T_51/93 *SERONO/Subcutaneous administration of human chorionic gonadotrophin*, unreported decision of the TBA dated 8 June 1994. See also T_138/95 *GENENTECH/Intrapulmonary Delivery*, unreported decision of the TBA dated 12 October 1999.

⁷² T_1399/04 *SCHERING CORPORATION/Combination Therapy HCV*, unreported decision of the TBA dated 25 October 2006.

⁷³ T_570/92 *BAYER/Nifedipin*, unreported decision of the TBA (available in German only) dated 22 June 1995.

⁷⁴ T_1642/06 *SPRUCE BARBARA/Sigma receptor* [2008] EPOR 12

⁷⁵ T_1020/03 *GENENTECH/Method of administration of IGF-I* [2006] EPOR 67.

⁷⁶ i.e. under the new Art 54(5) EPC 2000. This point is made clearly by the Technical Board of Appeal in Case T 1780/12 *UNIVERSITY OF TEXAS BOARD OF REGENTS/Cancer treatment* [2014] EPOR 28 esp. at [16]-[24]. Here the Board explained (in the context of a case on double patenting, but the point translates clearly into situations of infringement) that: “[P]urpose-limited process claims vs. purpose-limited product claim ... differ ... in at least one technical feature [the manufacture of a medicament]. It is generally accepted as a principle underlying the EPC that a claim to a particular physical activity (e.g. method, process, use) confers less protection than a claim to the physical entity per se.... It follows that a purpose-limited process claim also confers less protection than a purpose-limited product claim.” See point 22 of the Reasons for the Decision. More recently, in T_1021/11 *BOEHRINGER INGELHEIM/PCV2 composition* [2016] EPOR 9, one of the Technical Boards of the EPO was prepared to accept that for applications falling within the transitional window – i.e. applied for between the coming into force of the EPC 2000 and the proclaimed end of the Swiss-form’s reign following *ABBOTT* – it may be appropriate to include claims of both formats in the same patent. Evidently this would be pointless if the claims were of the same scope. See esp. points 34 to 49 of the Reasons for the Decision

⁷⁷ Art 123 EPC governs permissible amendments to the claims. Art 123(3) states quite simply that: “The European patent may not be amended in such a way as to extend the protection it confers.”

form is therefore definitively narrower than a use-bound product claim. In making this comment, the Board also classified the Swiss-form as a claim limited to a manufactured medicament “which is packaged and/or provided with instructions for use in the [specified] treatment.”⁷⁸ However, this singular comment is, at the time of writing, about as close as the Boards of Appeal have got to making any form of proclamation concerning the scope that the Swiss-form is to enjoy.

This interpretative vacuum was, however, only part of the problem. From a UK perspective the uncertainty brought by the Swiss-form claim was (and remains) compounded by aspects of the requirements, processes and procedures that accompany the marketing, prescription and dispensation of medicines. As we shall therefore see in Part II of this series, these elements serve to remove much of the control over infringement from the generic supplier and place it in the hands of others in the supply chain. Consideration of these factors is essential to understand the practical difficulties that accompany the isolation of a patented use of a medicinal compound that is otherwise in the public domain. With this in mind, we will therefore commence Part II by briefly discussing aspects of the regulatory framework for prescription medications in the UK. Following this, the remainder of the article will be dedicated to the question of infringement and the problems raised by retro-fitting use-limitations into this arena.

⁷⁸ T_1673/11 *GENZYME/Treatment of Pompe's disease* [2016] EPOR 33, at [24], Point 9.1 of the Reasons for Decision.